

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

REMARKS

Claims 1-25 are pending and stand rejected. Claims 1 and 15 have been amended. New claims 26-32 have been added. Reconsideration of the rejection is respectfully requested.

Claims 1-25 were rejected under 35 U.S.C. 112, first paragraph, as being non-enabling. Applicant respectfully traverses this rejection.

Before addressing the details of the rejection, applicant believes that a brief summary of the invention might be useful.

The claimed invention pertains to a process for making a porous polymer of some desired shape. The polymer is rendered in gel form so that it can be readily shaped, such as by injection molding. Particular shapes and structures that are of immediate utility to the assignee are prostheses for use in living beings, especially humans. Using the techniques taught in applicant's specification, one can incorporate one or more substances within the polymeric body such as pharmaceuticals, cells, hormones, antibiotics, etc. Further, one may incorporate another structure into the polymeric body, such as a suture or a reinforcing ring during the molding of the gel, for example, to form a "composite" structure of the shaped porous polymer, with the other structure mechanically attached to it.

Applicant's representative appreciates the courtesies extended by the examiner and the primary examiner during the telephonic interview on May 7, 2003. During this interview, applicant's representative stated that the application discloses not just a single working example on how to make a porous polyurethane, but broadly teaches a protocol for making a porous polymer using most any polymer of choice. At the same time, the Office expressed concern that the specification only sufficiently taught the process for three specific embodiments involving a polyurethane polymer. Further, the Office suggested that the claimed invention should reflect appropriate ratios of the solvents to the polymer. Lastly, the primary examiner was concerned that there might exist prior art that could render the claimed invention unpatentable. Thus, he requested that the examiner search the microcapsule and/or microsphere polymer art upon receipt of applicant's response to the outstanding Office Action. As a result of the interview, applicants better appreciate the concerns of the Office concerning the question of enablement. Accordingly, in addition to applicant's arguments, applicant has amended the claims to more precisely reflect the "screening protocol" portion of the claimed invention.

The examiner has the burden to make a prima facie case that the present application lacks enablement as required by §112. To support this prima facie case, the Action argues that the application is for *any* polymer, in combination with *any* first solvent and *any* second solvent. Respectfully, it is argued that the prima facie case is not appropriately stated. The Action misrepresents the scope of the claims, as the process is not for *any* polymer in combination with *any* two solvents. Rather, as stated in the application, the process relies on creating a gelled mixture, comprising a polymer, a first solvent, and a second solvent, wherein the

description has defined on page 4, line 35 – 41 a first solvent as a solvent that dissolves a polymer, and a second solvent is defined as a gelling solvent distinguished from a non-solvent.

Applicant agrees that In re Wands, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) is a seminal case on the subject of enablement, and that it represents the proposition that the issue of enablement embraces numerous factors.

The patent case law has also stated that a single embodiment may provide broad enablement in cases involving predictable factors, but that more is required for cases involving unpredictable factors, such as most chemical reactions and physiological activity. Ex parte Hitzeman, 9 USPQ2d 1821 (Bd. Pat App. & Int’l. 1988). While the chemistry in the present specification is not as complex, applicant respectfully submits, as in a case, for example, pertaining to the biologic activity of chemicals proposed as pharmaceuticals, applicant can agree in general that the present specification would not be enabled for a broad claim if all that it provided in the way of how to make the invention was a single working example and nothing more. However, applicant's specification does indeed provide more than this.

Specifically, the Example found on pages 11-13 of the specification has three subsets labeled Samples A, B and C, which show the production of three porous polyurethanes, by way of the use of three different gelling solvents. In effect, applicant has here provided three working examples. In addition, applicant has provided a Comparative Example, which shows a technique that does not produce the desired results. This, too, is highly instructive.

Thus, the Example and Comparative Example illustrate a technique for preparing the porous polyurethane polymer, which technique can be summarized as follows: (1) for any given polymer, identify at least one substance ("solvent") that dissolve the polymer, and at least one substance that merely swells the polymer without dissolving it; (2) then, treat the polymer with these solvents in sequential order, i.e., first dissolve the polymer to form a solution, and then treat the solution with the swelling solvent to thicken it to a gel; and (3) once the gel has been formed, shape or mold the gel, and then remove the solvents.

But even beyond this relatively simple procedure, what is significant is that applicant teaches not just a procedure for making porous polyurethane, but sets forth a broad technique or protocol for making a shaped porous structure of most any desired polymer. In other words, applicant expressly states the above general protocol for identifying the first and second solvents that are necessary to render a solid polymer in gel form, which is critical to the operation of the invention. See for example, page 11, lines 33-39, and page 12, lines 6-13 of the specification. What is especially significant here is that applicant is not just providing some specific chemical procedure, but rather is also providing the "why" of the procedure; he explains the thought process behind the mechanics of the screening technique, thereby making it generally applicable to other polymer/solvent systems, not just the system of polyurethane in tetrahydrofuran. Significantly, the case law states that the number and variety of examples are

irrelevant if the specification is enabling. In re Borkowski, 422 F.2d 904 at 910, 164 USPQ 642 at 646 (CCPA 1970).

Thus, applicant respectfully submits that broad claims are enabled because not only does the specification provide detailed Examples showing how the invention is carried out for one particular polymer, it also provides the general guidance on how to carry out the claimed method for any polymer selected. As the specification has indicated (for example, at page 11, line 33-38), it is not possible to identify every combination of polymer and solvents, but the specification teaches how to go about identifying suitable solvents.

Thus, the matter of identifying suitable first and second solvents is a matter of performing some screening runs. As the Example indicates, the effect of the candidate solvent on the solid polymer is quickly observed by mere visual inspection, e.g., dissolution, swelling, or neither. Accordingly, applicant respectfully submits that this kind of screening is routine. "...[Even] a considerable amount of experimentation is permissible, **if it is merely routine** ..." In re Wands, at 737.

Ranges

As for specifying ranges or ratios of the first and second solvents to the polymer, again, as with the issue of identifying combinations of first and second solvents for the polymer, it is impossible to provide specific numeric quantities for these ratios. See, for example, page 12, lines 25-28.

The claimed invention is still enabled, however, applicant respectfully submits. Specifically, (1) the specification provides guidance on what to expect as the amount of second solvent is increased; and (2) some ranges, such as that of the polymer in solution, are within the normal range of a polymer chemist's experience.

With specific regard to point (1), applicant notes that the data found within the Example can be used as a starting point for determining appropriate ranges. In particular, the polymer was 12.5% by weight in the first solution, and about 2% by weight after adding the second solvent.

With specific regard to point (2) above, applicant respectfully submits that the approximate maximum concentration of polymer that one can dissolve is well within the skilled artisan's knowledge and experience. Further, since the dissolution process is not new, this information is available in standard chemical reference books, e.g., CRC, Merck Index, etc. At the other extreme, from a chemical standpoint, there is no minimum concentration of polymer, i.e., corresponding to infinite dilution; however, applicant respectfully submits that the skilled artisan will realize that, for very dilute systems, the polymeric body that is recovered after removing the solvents may no longer be in one piece and self-supporting.

The specification provides further guidance on how much of the second solvent to add. Specifically, at page 5, line 46 – 52 it says that the solution thickens or increases in viscosity with increasing amounts of swelling solvent. Although this trend will not continue indefinitely, the specification informs the skilled artisan at what point to stop: when a stable gel has been formed, which can then be molded (see, for example, page 4, lines 41-43).

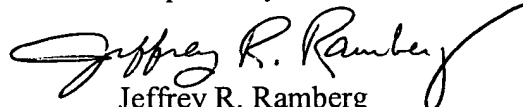
Thus, applicant respectfully submits that the present specification supports broad method claims because the specification provides more than enough guidance to enable an artisan of ordinary skill to apply the described screening protocol to most any polymer selected. Accordingly, applicant respectfully requests that the enablement rejection be withdrawn.

Applicant directs the attention of the examiner to the attached Information Disclosure Statement. Applicant respectfully submits that the references appended thereto were cited by a foreign patent office during corresponding foreign prosecution within the past three months. Accordingly, no fee should be due.

In view of the carefully amended claims and the above remarks, applicant respectfully submits that the present application is in condition for allowance. Accordingly, applicant respectfully requests issuance of a Notice of Allowance directed to claims 1-32.

Should the Examiner deem that any further action on the part of applicant would be desirable, the Examiner is invited to telephone applicant's undersigned representative.

Respectfully submitted,


Jeffrey R. Ramberg
Reg. No. 34,700

May 30, 2003

c/o Kensey Nash Corporation
55 East Uwchlan Avenue
Exton, PA 19341
Tel: (610) 594-4392
Fax: (610) 524-0265

Encl. (1) Appendix A: Current status of the claims
(2) Information Disclosure Statement

Appendix A

Current status of the claims

1 (Amended). A process for creating a porous polymeric body of desired shape, comprising the steps of:

- [a. dissolving a polymer in a first solvent to create a solution;
- b. adding a second solvent to the solution that causes the solvent/polymer solution to thicken into a gel;
- c. forming the gel into a desired shape; and
- d.]
- a. selecting a polymer;
- b. identifying a first solvent that is capable of substantially dissolving a solid form of the polymer;
- c. identifying a second solvent that does not substantially dissolve the polymer in solid form, but instead merely swells the solid polymer;
- d. providing at least sufficient first solvent to said polymer as to substantially dissolve the polymer in the first solvent to form a solution;
- e. adding a quantity of the second solvent to the solution, whereupon the solution begins to gel;
- f. continuing the adding of the second solvent until a viscosity of the gel increases to a point where the gel is suitable for shape-forming;
- g. shape-forming the gel; and
- h. removing the first and second solvents from the gel.

2 (Original). The process of claim 1, wherein forming of the polymer gel comprises spreading the gel onto an open smooth or textured surface.

3 (Original). The process of claim 1, wherein forming of the polymer gel comprises injecting the gel into a mold.

4 (Original). The process of claim 1, wherein forming of the polymer gel comprises spreading or injecting the gel over a three-dimensional object, and removing the three-dimensional object after removing the first and second solvent from the gel.

5 (Original). The process of claim 1, wherein forming of the polymer gel involves forcing a three-dimensional object into a volume of the gel, and removing the three-dimensional object after removing the first and second solvent from the gel.

6 (Original). The process of claim 1, wherein a biologically active agent is mixed with the polymer and first solvent prior to addition of the second solvent.

7 (Original). The process of claim 1, wherein a biologically active agent is mixed with the second solvent prior to addition to the first solvent/polymer solution.

8 (Original). The process of claim 1, wherein a biologically active agent is mixed with the gel prior to removal of the first and second solvents.

9 (Original). The process of claim 1, wherein a biologically active agent is incorporated within the pores of the polymeric body after removal of the first and second solvent.

10 (Original). The process of any of claims 6, 7, 8 or 9, wherein the biologically active agent is selected from one or more of the following: physiologically acceptable drugs, surfactants, ceramics, hydroxyapatites, tricalciumphosphates, antithrombogenic agents, antibiotics, biologic modifiers, glycosaminoglycans, proteins, hormones, antigens, viruses, cells or cellular components.

11 (Original). The process of claim 1, wherein the gel is placed in contact with a separate body, after which the first and second solvent are removed, leaving the porous polymer mechanically bound to the body.

12 (Original). The process of claim 1, wherein the polymer comprises a polyurethane.

13 (Previously amended). The process of claim 12, wherein the first solvent comprises at least one solvent selected from the group comprising dimethyl acetimide, n-methyl pyrrolidinone and tetrahydrofuran.

14 (Original). The process of claim 12, wherein the first solvent comprises tetrahydrofuran, and the second solvent comprises at least one solvent selected from the group comprising p-dioxane, dimethyl sulfoxide and o-xylene.

15 (Amended). A process for creating a composite body comprising a porous polymeric body using a gel enhanced phase separation technique, the process comprising the steps of:

- a. substantially dissolving a selected polymer in a suitable first organic solvent to form a solution;
- b. adding a suitable second solvent to the solution that causes the solvent/polymer solution to thicken into a gel;
- c. placing the gel in contact with at least one other material; and
- d. removing the first and second solvent, thereby leaving a porous polymer and the at least one other material, wherein said porous polymer and said at least one other material are mechanically bound to each other.

16 (Original). The process of claim 15, wherein the other material is biodegradable.

17 (Original). The process of claim 15, wherein the other material provides reinforcement to the porous polymer.

18 (Original). The process of claim 17, wherein the other material is in the form of reinforcing threads.

19 (Original). The process of claim 15, wherein the other material is in the form of reinforcing rings.

20 (Original). The process of claim 15, wherein the other material aids in attaching the porous polymer prosthesis to host tissue.

21 (Original). The process of claim 16, wherein the other material is in the form of a suture.

22 (Original). The process of claim 16, wherein the other material is in the form of a tack.

23 (Original). The process of claim 15, wherein the other material is a biologically active agent.

24 (Original). The process of claim 23, wherein the biologically active agent is selected from one or more of the following: physiologically acceptable drugs, surfactants, ceramics, hydroxyapatites, tricalciumphosphates, antithrombogenic agents, antibiotics, biologic modifiers, glycosaminoglycans, proteins, hormones, antigens, viruses, cells or cellular components.

25 (Original). The process of claim 15, wherein the composite body is a component of a larger body.

26 (New). The process of claim 15, wherein the selected polymer comprises a polyurethane.

27 (New). The process of claim 26, wherein the first solvent comprises at least one solvent selected from the group comprising dimethyl acetamide, n-methyl pyrrolidinone and tetrahydrofuran.

28 (New). The process of claim 26, wherein the first solvent comprises tetrahydrofuran, and the second solvent comprises at least one solvent selected from the group comprising p-dioxane, dimethyl sulfoxide and o-xylene.

29 (New). The process of claim 1, wherein the polymer comprises at least one polymer selected from the group consisting of polyureas, polyethylenes, polyesters and fluoropolymers.

30 (New). The method of claim 1, wherein said first solvent comprises an organic solvent selected from the group consisting of acetone, chloroform, p-dioxane, methylene chloride, n,n-dimethyl acetimide, dimethyl sulfoxide, 1-methyl-2-pyrrolidone, tetrahydrofuran, toluene, m-xylene, o-xylene, and methyl-ethyl-ketone.

31 (New). The method of claim 1, wherein said second solvent comprises an organic solvent selected from the group consisting of acetone, chloroform, p-dioxane, methylene chloride, n,n-dimethyl acetimide, dimethyl sulfoxide, 1-methyl-2-pyrrolidone, tetrahydrofuran, toluene, m-xylene, o-xylene, and methyl-ethyl-ketone.

32 (New). A process for creating a porous polyurethane body, comprising the steps of:

- a. dissolving a solid polyurethane polymer in a suitable first solvent to create a solvent/polyurethane solution;
- b. adding a suitable second solvent to the solution, thereby causing the solvent/polyurethane solution to thicken into a gel;
- c. forming the gel into a desired shape; and
- d. removing the first and second solvent from the gel, thereby leaving behind a shaped, porous polyurethane body.